

REMARKS

In the Office Action, the Specification including the Abstract is objected; claims 1-6 are rejected under 35 U.S.C. § 101; claims 1-6 and 18 are rejected under 35 U.S.C. § 112, first paragraph; claims 1-22 are rejected under 35 U.S.C. § 112, second paragraph; claims 1-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting; and claims 1-22 are rejected under 35 U.S.C. § 102 or § 103. Claims 1, 2, 4, 5, 7-9, 11-18, 20 and 21 have been amended. Applicants believe that the rejections have been overcome or are improper in view of the amendments and for the reasons set forth below.

At the outset, the Specification including the Abstract has been objected as previously discussed. In response, Applicants have amended the Specification including the Abstract and as such believe that the objections have been addressed. Therefore, Applicants respectfully request that the objections to the Specification including the Abstract be withdrawn.

In the Office Action, claims 1-6 are rejected under 35 U.S.C. § 101. In response, Applicants have amended independent claim 1 to recite a biologically pure culture of lactic acid bacterium strain. Therefore, Applicants believe that the requirements pursuant to 35 U.S.C. § 101 have been satisfied.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 1-6 and 18 are rejected under 35 U.S.C. § 112, first paragraph. The Patent Office asserts that the microorganism recited in the claims must be obtainable by a repeatable method set forth in the Specification or otherwise be readily available to the public. However, this requirement may be satisfied by a deposit of a microorganism. In this regard, Applicants respectfully submit that a deposit of the microorganism, namely, *Lactobacillus paracasei* CNCM I-2116 (NCC 2461) has been made pursuant to PCT Rule 13 *bis* during the examination of the related International Application No. PCT/EP00/01798. A copy of a document relating to the deposit as discussed above is attached herewith as Exhibit A. Therefore, Applicants believe that the requirements pursuant to the first paragraph of 35 U.S.C. § 112 have been satisfied.

Accordingly, Applicants believe that the rejection of claims 1-6 and 18 under 35 U.S.C. § 112, first paragraph be withdrawn.

In the Office Action, claims 1-22 are rejected under 35 U.S.C. § 112, second paragraph. In response, claims 1, 2, 4, 5, 7-9, 11-18, 20 and 21 have been amended to address most of the issues raised with respect to this rejection. In this regard, Applicants believe that these changes were made for clarification purposes and thus assert that the changes should not be deemed as an intention on the part of Applicants to narrow or disclaim any claimed subject matter in view of same. Further, the Patent Office alleges that claims 7-10 are rendered vague and indefinite for failing to set forth clear and distinct processing steps; that claims 11 and 13 are rendered vague and indefinite for failing to set forth how “administering” is being carried out and clear and distinct processing steps; that claim 12 is vague and indefinite in that the form of the composition is allegedly unclear; that claim 20 is considered vague and indefinite as failing to set forth a positive and clear step for “administering”; and that claim 21 is considered unclear as to the type of food. Applicants believe that these alleged clarity issues with respect to claims 7-13, 20 and 21 are improper. In this regard, Applicants believe that the claimed subject matter at issue is fully supported in the Specification in such a way that one skilled in the art would understand the scope and content of the subject matter as claimed.

Based on at least these reasons, Applicants believe that the requirements pursuant to 35 U.S.C. § 112, second paragraph, have been satisfied. Therefore, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 1-22 have been rejected under 35 U.S.C. § 102 or § 103 in view of EP 0861905. Applicants believe that this rejection should be withdrawn as set forth below.

Of the pending claims at issue, claims 1, 7, 9, 11, 12, 20 and 21 are the sole independent claims. Independent claim 1 recites a biologically pure culture of lactic acid bacterium strain belonging to a genus Lactobacillus that has the ability to prevent colonization of an intestine with pathogenic bacteria causing diarrhoea and of preventing infection of intestinal epithelial cells by rotaviruses wherein the lactic acid bacterium strain is capable of growing in presence of up to 0.4% bile salts. Claim 7 recites a method for preparing an ingestable support that uses the biologically pure culture of lactic acid bacterium strain. Claim 9 recites a method for preparing an ingestable support material that uses a supernatant of a biologically pure culture of the lactic acid bacterium strain. Claim 11 recites a method for treatment of a disorder associated with

diarrhoea that includes administering to a patient having a disorder the biologically pure culture of lactic acid bacterium strain. Claim 12 recites a pharmaceutical composition that contains a biologically pure culture of lactic acid bacterium strain. Claim 20 recites a method for preventing a disorder associated with diarrhoea that includes administering the biologically pure culture of lactic acid bacterium strain. Claim 21 recites a food that includes a biologically pure culture of lactic acid bacterium strain.

The microorganisms of the present invention have been shown to exhibit a number of desirable properties. They are gram positive, catalase negative, NH₃ form arginine negative and carbon dioxide production negative. The microorganisms can produce L(+) lactic acid and are capable of growth in the presence of bile salts in a concentration of up to about 0.4% and may effectively prevent infection of epithelial cells by rotaviruses. See, Specification, p. 3, lines 21-25.

In contrast, applicants believe that the cited art is deficient with respect to the claimed invention.

The cited reference fails to provide any suggestion against which agents the lactobacilli are providing any activity. In this regard, the cited reference merely discloses that strains are opposing pathogens purportedly through a lowering of the pH of the intestinal environment. See, EP0861905, page 4, lines 33-35. Indeed, the term "pathogens" is not specifically defined and may therefore relate to parasites, fungi, bacteria, viruses or even to inorganic particles. Moreover, nowhere does the cited art disclose or suggest viruses including rotaviruses and bacteria-causing diarrhea as claimed. The primary focus of the cited art relates to lactic acid bacteria that are purportedly designed to reconstitute the microflora that has been lost during antibiotic treatment or after anti-tumor radiotherapy. Thus, the cited reference fails to disclose or suggest how to protect intestinal epithelial cells against infection by rotaviruses and pathogenic bacteria.

Further, rotaviruses exhibit a relatively high stability and would not be affected by a relatively slow lowering of the pH of the extracellular intestinal environment caused by organic acids as disclosed in the cited reference. The cited reference also fails to disclose or suggest lactobacillus strains that are capable of growth in the presence of up to 0.4% bile salts as claimed. Therefore, Applicants believe that one skilled in the art would conclude that the strains

as disclosed in the cited reference do not exhibit any protective property against an infection of the human intestine by rotaviruses and bacteria as required by the claimed invention.

Based on at least these reasons, Applicants believe that the cited reference is deficient with respect to the claimed invention. Therefore, Applicants believe that the cited reference fails to disclose or suggest claimed invention.

Accordingly, Applicants respectfully request that the anticipation and obviousness rejections in view of EP0861905 be withdrawn.

Claims 1-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting. More specifically, claims 1-22 are provisionally rejected as allegedly being unpatentable over claims 1-22 of copending application No. 09/936,489 and copending application No. 09/936,453. As the obviousness-type double patenting rejections are provisional, Applicants assert that they plan to submit a terminal disclaimer, if necessary, to overcome the provisional rejections once either one or both of the copending applications have issued. Therefore, Applicants believe that they have been responsive to the provisional rejections at this stage in the prosecution.

For the foregoing reasons, applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration for the same.

Respectfully submitted,

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Dated: December 30, 2003

Applicant's or agent's
file reference

80248/WO

International application No.

PCT/EP00/01798

**INDICATIONS RELATING TO DEPOSITED MICROORGANISM
OR OTHER BIOLOGICAL MATERIAL**

(PCT Rule 13bis)

A. The indications made below relate to the deposited microorganism or other biological material referred to in the description on page 3, line 30, page 5, line 8, page 7, line 12, page 22, line 22

B. IDENTIFICATION OF DEPOSIT

Further deposits are identified on an additional sheet

Name of depositary institution

CNCM

Collection Nationale de Cultures de Microorganismes

Address of depositary institution (including postal code and country)

Institut Pasteur
28, Rue du Docteur Roux
F-75724 Paris Cedex 15

Date of deposit

12.01.1999

Accession Number

I-2116

C. ADDITIONAL INDICATIONS (leave blank if not applicable)

This information is continued on an additional sheet

D. DESIGNATED STATES FOR WHICH INDICATIONS ARE MADE (if the indications are not for all designated States)

E. SEPARATE FURNISHING OF INDICATIONS (leave blank if not applicable)

The indications listed below will be submitted to the International Bureau later (specify the general nature of the indications e.g. "Accession Number of Deposit")

For receiving Office use only

This sheet was received with the international application

For International Bureau use only

This sheet was received by the International Bureau on:

Authorized officer

Authorized officer

TRAITE DE BUDAPEST SUR LA RECONNAISSANCE
INTERNATIONALE DU DEPOT DES MICRO-ORGANISMES
AUX FINS DE LA PROCEDURE EN MATIERE DE BREVETS

FORMULE INTERNATIONALE

DESTINATAIRE :

RECEPISSE EN CAS DE DEPOT INITIAL,
délivré en vertu de la règle 7.1 par
l'AUTORITE DE DEPOT INTERNATIONALE
identifiée au bas de cette page

SOCIETE DES PRODUITS NESTLE S.A.
Patents department
Avenue Nestlé 55
CH-1800 Vevey

**NOM ET ADRESSE
DU DEPOSANT**

I. IDENTIFICATION DU MICRO-ORGANISME

Référence d'identification donnée par le
DEPOSANT :

NCC 2461

Numéro d'ordre attribué par
l'AUTORITE DE DEPOT INTERNATIONALE :

I - 2116

II. DESCRIPTION SCIENTIFIQUE ET/OU DESIGNATION TAXONOMIQUE PROPOSEE

Le micro-organisme identifié sous chiffre I était accompagné :

- d'une description scientifique
- d'une désignation taxonomique proposée

(Cocher ce qui convient)

III. RECEPTION ET ACCEPTATION

La présente autorité de dépôt internationale accepte le micro-organisme identifié sous
chiffre I, qu'elle a reçu le **12 JANVIER 1999** (date du dépôt initial)¹

IV. RECEPTION D'UNE REQUETE EN CONVERSION

La présente autorité de dépôt internationale a reçu le micro-organisme identifié sous
chiffre I le **12 JANVIER 1999** (date du dépôt initial)
et a reçu une requête en conversion du dépôt initial en dépôt conforme au Traité de
Budapest le **12 FÉVRIER 1999** (date de réception de la requête en conversion)

V. AUTORITE DE DEPOT INTERNATIONALE

| | | |
|------------------|------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Nom : | CNCM Collection Nationale de Cultures de Microorganismes | Signature(s) de la (des) personne(s) compétente(s) pour représenter l'autorité de dépôt internationale ou de l'(des) employé(s) autorisé(s) : Mme Y. CERISIER <small>Directeur Administratif de la CNCM</small> |
| Adresse : | INSTITUT PASTEUR 28, Rue du Docteur Roux F-75724 PARIS CEDEX 15 |  Date : Paris, le 12 février 1999 |

¹ En cas d'application de la règle 6.4.d), cette date est la date à laquelle le statut
d'autorité de dépôt internationale a été acquis.